Complete Summary

GUIDELINE TITLE

Premature cervical dilatation.

BIBLIOGRAPHIC SOURCE(S)

Fleischer AC, Andreotti RF, Bohm-Velez M, Fishman EK, Horrow MM, Hrocak H, Thurmond A, Zelop C, Expert Panel on Women's Imaging. Premature cervical dilation. [online publication]. Reston (VA): American College of Radiology (ACR); 2005. 7 p. [27 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Laing F, Mendelson E, Bohm-Velez M, Bree RL, Finberg H, Fishman EK, Hricak H, Sartoris D, Thurmond A, Goldstein S. Premature cervical dilatation. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun 1;215(Suppl):939-45.

The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

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SCOPE

DISEASE/CONDITION(S)

Premature cervical dilatation (cervical incompetence)

GUIDELINE CATEGORY

Diagnosis Prevention

CLINICAL SPECIALTY

Obstetrics and Gynecology Radiology

INTENDED USERS

Health Plans
Hospitals
Managed Care Organizations
Physicians
Utilization Management

GUI DELI NE OBJECTI VE(S)

To evaluate the appropriateness of initial radiologic examinations for premature cervical dilatation (cervical incompetence)

TARGET POPULATION

Patients with premature cervical dilatation (cervical incompetence)

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Transabdominal scan (bladder full or bladder empty)
- 2. Translabial/transvaginal sonography
- 3. Multiple looks versus single look at cervix during ultrasound (US) exam
- 4. Reporting of cervical length in mm or cm
- 5. Reporting of endocervical diameter in mm (if dilated)
- 6. Sonographic cervical stress test

MAJOR OUTCOMES CONSIDERED

Utility of radiologic examinations in diagnosis of preterm cervical dilation

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of peer-reviewed medical journals, and the major applicable articles were identified and collected.

NUMBER OF SOURCE DOCUMENTS

The total number of source documents identified as the result of the literature search is not known.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVI DENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed for reaching agreement in the formulation of the appropriateness criteria. The American College of Radiology (ACR) Appropriateness Criteria panels use a modified Delphi technique to arrive at consensus. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by the participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1 to 9, indicating the least to the most appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty (80) percent agreement is considered a consensus. This modified Delphi technique enables individual, unbiased expression, is economical, easy to understand, and relatively simple to conduct.

If consensus cannot be reached by this Delphi technique, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible. If "No consensus" appears in the rating column, reasons for this decision are added to the comment sections.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria®

<u>Clinical Condition</u>: Premature Cervical Dilatation

<u>Variant 1</u>: Patient not at risk for preterm delivery: 18 weeks gestation: by transabdominal scan cervix \leq 2.5 cm long.

Radiologic Exam Procedure	Appropriateness Rating	Comments
	Ultrasc	ound
Report specific cervical length in mm or cm	9	
Transabdominal followed by translabial or transvaginal	8	
Multiple looks at cervix during US exam	8	
Report endocervical diameter in mm (if dilated)	8	

Radiologic Exam Procedure	Appropriateness Rating	Comments
Transabdominal scan only - bladder full	2	
Transabdominal scan only - bladder empty	2	
Single look at cervix during US exam	2	
Sonographic cervical stress test	No Consensus	May identify patients requiring treatment for preterm cervical dilation. See the summary below.
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1 = Least appropriate 9 = Most appropriate		

<u>Variant 2</u>: Patient at risk for preterm delivery (history of 3 prior midtrimester spontaneous losses): 18 weeks gestation: by transabdominal scan cervix \leq 3.8 cm long.

Radiologic Exam Procedure	Appropriateness Rating	Comments
	Ultrasc	ound
Report specific cervical length in mm or cm	9	
Multiple looks at cervix during US exam	8	
Report endocervical diameter in mm (if dilated)	8	
Transabdominal scan only - bladder empty	6	
Transabdominal followed by translabial or transvaginal	6	
Transabdominal scan only - bladder full	2	
Single look at cervix	2	

Radiologic Exam Procedure	Appropriateness Rating	Comments
during US exam		
Sonographic cervical stress test	No Consensus	May identify patients requiring treatment for preterm cervical dilation. See the summary below.
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1 = Least appropriate 9 = Most appropriate		

<u>Variant 3</u>: Patient at no risk for preterm delivery: 18 weeks gestation: by transabdominal scan cervix \leq 3.8 cm long.

Radiologic Exam Procedure	Appropriateness Rating	Comments
	Ultrasc	bund
Transabdominal scan only	8	
Single look at cervix during US exam	8	
Report endocervical diameter in mm (if dilated)	8	
Transabdominal followed by translabial or transvaginal	2	
Sonographic cervical stress test	2	
Multiple looks at cervix during US exam	2	
Report specific cervical length in mm or cm	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1 = Least appropriate 9 = Most appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

<u>Variant 4</u>: Patient not at risk for preterm delivery: 28 weeks gestation: by transabdominal scan cervix \leq 2.5 cm long.

Radiologic Exam Procedure	Appropriateness Rating	Comments	
	Ultrasound		
Report specific cervical length in mm or cm	9		
Transabdominal followed by translabial or transvaginal	8		
Multiple looks at cervix during US exam	8		
Report endocervical diameter in mm (if dilated)	8		
Transabdominal scan only - bladder full	2		
Transabdominal scan only - bladder empty	2		
Single look at cervix during US exam	2		
Sonographic cervical stress test	No Consensus	May identify patients requiring treatment for preterm cervical dilation. See the summary below.	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1 = Least appropriate 9 = Most appropriate			

<u>Variant 5</u>: Patient at risk for preterm delivery (history of 3 prior midtrimester spontaneous loses): 28 weeks gestation: by transabdominal scan cervix \leq 3.8 cm long.

Radiologic Exam Procedure	Appropriateness Rating	Comments
Ultrasound		
Report specific cervical length in mm or cm	9	

Radiologic Exam Procedure	Appropriateness Rating	Comments
Multiple looks at cervix during US exam	8	
Report endocervical diameter in mm (if dilated).	8	
Transabdominal scan only - bladder empty	6	
Transabdominal followed by translabial or transvaginal	6	
Transabdominal scan only - bladder full	2	
Single look at cervix during US exam	2	
Sonographic cervical stress test	No Consensus	May identify patients requiring treatment for preterm cervical dilation. See the summary below.
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1 = Least appropriate 9 = Most appropriate		

<u>Variant 6</u>: Patient at no risk for preterm delivery: 28 weeks gestation: by transabdominal scan cervix \leq 3.8 cm long.

Radiologic Exam Procedure	Appropriateness Rating	Comments
	Ultrasc	ound
Transabdominal scan only	8	
Single look at cervix during US exam	8	
Report endocervical diameter in mm (if dilated)	8	
Transabdominal	2	

Radiologic Exam Procedure	Appropriateness Rating	Comments
followed by translabial or transvaginal		
Sonographic cervical stress test	2	
Multiple looks at cervix during US exam	2	
Report specific cervical length in mm or cm	2	

Appropriateness Criteria Scale
1 2 3 4 5 6 7 8 9
1 = Least appropriate 9 = Most appropriate

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

The term cervical incompetence was first introduced in 1948. This condition, which is characterized by painless midtrimester cervical dilatation, has a reported incidence of 1% and may be responsible for as many as 20% of second trimester miscarriages.

As a result of recent investigations that recognize features shared by women with cervical incompetence and those with premature labor, the concept of cervical incompetence as an "all or none" phenomenon has been challenged. Cervical incompetence is believed to represent a continuum that relates to cervical length and pregnancy history.

Regardless of the precise definition for this condition, there is no debate that preterm birth (<37 weeks of gestation) continues as the leading cause of perinatal morbidity and mortality. Consequently, it remains a major obstetrical challenge. Various methods for diagnosing preterm cervical dilatation have been proposed.

Digital Examination

Initial assessment is usually clinical and is based on digital palpation of the cervix. This examination can detect changes in cervical texture such as softening (which occurs as a precursor to delivery), and it can appreciate distensibility of the external os. These findings occur relatively late in the process of cervical dilatation, however, and in some cases are found too late to be reversed. Further, some physicians question the accuracy of digital measurements, which consistently underestimate measurements made by translabial or transvaginal ultrasound. Most likely, this inaccuracy is due to the anatomic configuration of the cervix because the portion of cervix that lies above the anterior fornix or above the bladder base is hidden from the examiner's fingers. The digital examination has other limitations: 1) it is a subjective assessment; 2) the internal cervical os, which reflects initial changes associated with premature cervical dilatation, is

beyond the examiner's reach; and 3) there are potential side effects that include risk of infection and ruptured membranes.

Nonetheless, if a patient is clinically at risk for preterm delivery, or if the ultrasound examination detects a short cervical length, some obstetriciangynecologists may perform a digital cervical examination. If she is near term (>37 weeks), however, this examination can be omitted, unless clinically indicated for other reasons. To optimize the results and patient management, it is important to correlate the findings of the ultrasound examination with the digital examination.

Sonographic Examination

Unlike digital examination, sonographic measurement of cervical length generates an image that may be reviewed and standardized, thus overcoming subjectivity.

Normal appearing cervix: During pregnancy, the length of the cervix does not elongate appreciably. Most authorities consider 3.0 cm in length as the lower limit of normal. In one large prospective, multicenter study, 4.0 cm was reported as the 75th percentile, 3.5 cm as the 50th percentile, 3.0 cm as the 25th percentile, and 2.6 as the 10th percentile.

Transabdominal evaluation: Because most obstetrical sonographic examinations are done transabdominally, this method remains the most common, even though it is the least reliable imaging method for evaluating the cervix. Using this approach, bladder overdistension can compress the walls of the lower uterine segment and cervix, creating a deceivingly normal appearance in women with cervical effacement, shortening, or frank dilatation. Furthermore, an underdistended bladder may preclude adequate cervical visualization for any one of a variety of reasons: acoustic shadowing from the pubic symphysis, refractive shadowing from the bladder-uterine interface, and loss of the acoustic window provided by the urinary bladder and/or amniotic fluid, or an inability to elevate the fetal head or other presenting part. Even when visible on a transabdominal scan, the cervical image is usually suboptimal. Because the external os is often not clearly identified, a technically correct cervical length measurement may not be possible. Aside from women near term (>37 weeks), if a patient has a clinical history or sonographic findings suspicious for cervical pathology, consideration should be given to additional scanning using either a transperineal or transvaginal approach. Rarely, in an at-risk patient, the entire cervix is clearly visible on a technically adequate transabdominal examination, in which case the translabial/transvaginal scan may be omitted. If a patient is not at risk, and has a normal-appearing cervix on transabdominal scans (with an empty or minimally filled bladder), it is not necessary to proceed to translabial/transvaginal imaging.

Translabial/transvaginal evaluation: These approaches are the most accurate for assessing the cervix. Cervical length is determined as the distance between the internal and external os. The internal os is normally at the level where the cervical canal meets the amniotic sac. The external os is often more difficult to precisely define because of acoustic shadowing from rectal gas. This problem can be minimized by either scanning the patient in a lateral decubitus position or elevating the hips and buttocks on a thick pad or pillow.

In patients at risk for cervical shortening or incompetence, some investigators suggest performing a cervical "stress test" by either applying transfundal pressure while scanning transvaginally, or by examining the patient while she is standing. Because some patients will initially have a completely normal-appearing cervix, these important maneuvers may identify additional women who may require treatment for preterm cervical dilatation. If the cervix is already dilated or short, the cervical stress test may not be necessary because it may compound the problem by inducing further dilatation and shortening.

Abnormal-appearing cervix: Although the clinical presentation varies, from an imager's point of view cervical changes are essentially identical in patients in term labor, preterm labor, or cervical incompetence. In each of these clinical situations, cervical dilatation begins proximally, at the level of the internal os, and progresses distally. As the internal os dilates, membranes and amniotic fluid invaginate into the proximal endocervical canal. The most accepted terminology for these changes is funneling, although wedging or beaking have also been used. Eventually the entire endocervical canal becomes filled with fluid, and if the membranes remain intact, they may be visible bulging into the vagina. Concurrent with dilatation, the cervix becomes effaced and shortened. Dilatation and effacement typically progress simultaneously, although, in a given patient, one or the other event may appear to predominate. In fact, in a series of patients with short cervices (<2.5 cm in length), funneling correlated with earlier delivery as well as higher neonatal mortality and morbidity.

Investigators have recommended quantitating these cervical changes using a variety of measuring techniques, but the simplest and most reproducible measurement in sensitivity and predictive value appears to be the residual closed length of the cervix. This calculation, which takes into account both dilatation and effacement, can be obtained by measuring from the distal apex of endocervical funneling at the internal os to the external os. Analysis supports 3.0 cm as the optimal cutoff to maximize sensitivity and specificity for predicting premature delivery. One investigation showed that all 24 subjects who delivered prematurely had a cervical length of less than 3.0 cm, and none of 15 women who had a cervical length of at least 3.0 cm delivered spontaneously before 36 weeks.

If a woman is clinically at risk for preterm delivery, or if a short cervix is detected by sonography, the precise length of the cervix should be measured and reported (this measurement is usually based on translabial or transvaginal scans). Studies have shown that serial transvaginal surveillance of cervical length in patients followed by cervical cerclage when cervical changes are encountered appears to reduce the cerclage rate without compromising pregnancy outcome. In addition, in cases with visible dilatation, sonologists should report the maximal endocervical diameter. The percent of "effacement" based on sonographic images is not reliable, because it is not possible to determine the location of the internal os once dilatation becomes apparent.

Pitfalls: A false diagnosis of preterm cervical dilatation may be made on a transabdominal scan in a patient who has a resolving lower uterine segment contraction, or whose cervix is vertically oriented (typically with a nondistended maternal bladder), and lacks prominent endocervical mucus. Under these circumstances, the glandular tissue circumferentially surrounding the endocervical canal can appear quite sonolucent and mimic endocervical fluid. These false

positive errors can be avoided if a patient with suspicious findings on transabdominal images is reevaluated using a translabial or transvaginal approach. A false diagnosis of preterm cervical shortening may occur on a translabial scan if rectal gas obscured the external os.

False negative diagnoses can occur during transperineal or transvaginal scanning if a cervical stress test is omitted. One of the most challenging groups of patients to evaluate are those in whom the appearance of the cervix changes during the sonographic examination. These transient but important observations underscore the need to observe the appearance of the cervix several times during a single obstetrical sonographic study, and suggest that a single image of the cervix may be insufficient for thorough cervical evaluation. This is particularly the case in women at-risk for preterm delivery, or those in whom a short cervix is detected by sonography. When a woman has transitory cervical changes, the minimal length of residual cervix should be reported and the patient should be considered at risk. Clinical follow-up of these women reveals that 61% to 74% have preterm labor or deliver prematurely.

Conclusion

Translabial and transvaginal sonography can each provide unique information about the cervix, that otherwise might not be readily available. These examinations are easy to perform, and in the appropriate clinical setting, should become an integral part of the sonographic study.

Abbreviations

• US, ultrasound

CLINICAL ALGORITHM(S)

Algorithms were not developed from criteria guidelines.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Selection of appropriate radiologic imaging procedures of patients with premature cervical dilatation (<37 weeks of gestation)

POTENTIAL HARMS

There is potential for a false diagnosis (false positive) on a transabdominal scan or for a failure to diagnose (false negative) preterm cervical dilatation during transperineal or transvaginal scanning. See "Major Recommendations" above under "Pitfalls" for details.

QUALIFYING STATEMENTS

OUALIFYING STATEMENTS

An American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Staying Healthy

IOM DOMAIN

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Fleischer AC, Andreotti RF, Bohm-Velez M, Fishman EK, Horrow MM, Hrocak H, Thurmond A, Zelop C, Expert Panel on Women's Imaging. Premature cervical dilation. [online publication]. Reston (VA): American College of Radiology (ACR); 2005. 7 p. [27 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 (revised 2005)

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

GUIDELINE COMMITTEE

Committee on Appropriateness Criteria, Expert Panel on Women's Imaging

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Arthur C. Fleischer, MD; Rochelle F. Andreotti, MD; Marcela Böhm-Vélez, MD; Elliot K. Fishman, MD; Mindy M. Horrow, MD; Hedvig Hricak, MD, PhD; Amy Thurmond, MD; Carolyn Zelop, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

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The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology Web site.

ACR Appropriateness Criteria® Anytime, Anywhere $^{\text{TM}}$ (PDA application). Available from the <u>ACR Web site</u>.

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

 ACR Appropriateness Criteria®. Background and development. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the <u>American College of Radiology (ACR) Web site</u>

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on December 28, 2000. The information was verified by the guideline developer on January 25, 2001. This NGC summary was completed by ECRI on January 31, 2006.

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